UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

In re Novartis and Par Antitrust Litigation	**1:18-cv-04361-AKH**
This Document Relates To: **All Actions**	

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' MOTION TO COMPEL THIRD PARTY ALEMBIC TO PRODUCE DOCUMENTS RESPONSIVE TO SUBPOENA

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I. INTRODUCTION

Direct Purchaser Plaintiffs, Retailer Plaintiffs, and End-Payor Plaintiffs (collectively, "Plaintiffs") move to compel Alembic to produce documents requested by Plaintiffs' subpoena. Plaintiffs served the subpoena more than eight months ago and Alembic has failed to produce a single document in response.

Plaintiffs allege that Defendant Novartis entered into an anticompetitive agreement with Defendant Par whereby Par agreed to delay its launch of generic Exforge until September 30, 2014 in exchange for Novartis' agreement not to launch its authorized generic version of Exforge until Par's generic had been on the market for six months. Dkt. No. 47, Am. Complaint, ¶ 6.[1] Because Par was eligible for a 180-day exclusive marketing period as the first to file generic applicant, Par's agreement not to launch its generic Exforge created a bottleneck that prevented subsequent generic applicants, like Alembic, from obtaining FDA approval to sell generic Exforge until the exclusivity's expiration. *Id*. at ¶¶ 11, 132-137. Thus, Plaintiffs have alleged that Par's and Novartis's agreement to delay the launch of generic Exforge until September 30, 2014 also delayed other generic companies, like Alembic, from obtaining approval for and launching generic Exforge until March 30, 2015 (181 days after Par's generic Exforge launch). In other words, Defendants' agreement delayed not just Par's and the authorized generic's launches, but also the launch of other generics, like Alembic, which injured Plaintiffs because generic Exforge prices would have been lower with more generics on the market. *Id*. at ¶¶ 11, 135-137.

Consequently, whether Alembic would have been ready, willing and able to market generic Exforge earlier than March 2015, when Par's 180-day exclusivity period ended, is

[1] Cites to the "Am. Complaint" are to the Direct Purchaser Plaintiffs' complaint. End-Payor Plaintiffs' and Retailer Plaintiffs' complaints allege the same unlawful conduct.

relevant to whether the Defendants' agreement caused Plaintiffs economic harm, and relevant to the quantum of damages. *See, e.g.*, *In re Namenda Direct Purchaser Antitrust Litig.*, 331 F. Supp. 3d 152, 172, 175-76 (S.D.N.Y. 2018) ("*Namenda I*") (evidence of other generics' ability to enter earlier "but for the settlement of the patent suit" is relevant and admissible at trial, and is a proper input to quantify damages); *In re Neurontin Antitrust Litig.*, Master Docket No. 02-1390 (FSH), 2013 WL 4042460, at *9-10 (D.N.J. Aug. 8, 2013) (defendant unsuccessfully argued at summary judgment that "Plaintiffs cannot establish that any alleged antitrust misconduct caused their injury because" generic manufacturer "did not obtain FDA approval" in time).

In addition, Alembic's expectations and understanding—as an informed and interested market participant—regarding how generic Exforge competition would occur absent the challenged conduct is relevant evidence of what would have happened absent Novartis's large payment to Par for delay. Alembic's data showing its sales of generic Exforge are likewise relevant to Plaintiffs' proof of antitrust impact and calculation of damages because it will be used to show Plaintiffs' purchases of generic Exforge and prices paid for generic Exforge.

To obtain this relevant evidence from Alembic, Plaintiffs served a subpoena seeking, *inter alia*, manufacturing, business, and regulatory documents, showing Alembic's generic Exforge planning, capacity, and launch preparation actions, as well as Alembic's sales forecasts and transactional data reflecting Alembic's actual generic Exforge sales.

Despite the clear relevance of Alembic's documents and several rounds of negotiations, during which Plaintiffs agreed to significantly narrow their requests, Alembic has not produced a single document in response to the subpoena and has unilaterally discontinued meet and confer discussions. This motion seeks to compel Alembic to produce the following five categories of documents that the subpoena requested but that Alembic has not produced: (a) Alembic's

generic Exforge sales data; (b) relevant documents from Alembic's Abbreviated New Drug Application ("ANDA") file for its generic Exforge product; (c) Alembic's documents relating to manufacturing capabilities, launch planning, and launch decision making; (d) Alembic's projections and other forecasting documents regarding the potential market entry of generic versions of Exforge; and (e) Alembic's Paragraph IV notice to Novartis challenging Novartis's patent(s) related to Exforge. These documents are relevant and Alembic has not shown that it would be unduly burdensome for Alembic to produce them.

Accordingly, Plaintiffs respectfully request that the Court order Alembic to promptly produce these five categories of documents, which are responsive to Plaintiffs' subpoena Request Nos. 1, 2, 3, 4, 5, 7, 12, and 13, as more fully described below.

II. BACKGROUND

On November 21, 2018, Plaintiffs served a Rule 45 subpoena on Alembic, to be answered by December 12, 2018. *See* Ex. 1.[2] Alembic served its objections and responses to the subpoena on December 12, 2018. *See* Ex. 2. Thereafter, Plaintiffs and Alembic communicated multiple times through letters and telephone conferences in an attempt to resolve Alembic's objections, including the following communications:

- December 20, 2018 (telephone conference);[3]
- January 16, 2019 (Alembic's email to Plaintiffs (Ex. 3);
- February 22, 2019 (Plaintiffs' letter to Alembic (Ex. 4));
- March 14, 2019 (Alembic's email to Plaintiffs (Ex. 3));
- March 29, 2019 (Plaintiffs' email to Alembic (Ex. 3));
- April 30, 2019 (Plaintiffs' email to Alembic (Ex. 3));
- May 10, 2019 (Plaintiffs' email to Alembic (Ex. 3));
- May 20, 2019 (telephone conference);
- May 31, 2019 (Plaintiffs' letter to Alembic (Ex. 5)); and
- July 16, 2019 (Plaintiffs' email to Alembic (Ex. 3)).

[2] Exhibits referenced herein are attached to the Declaration of Dan Litvin, filed contemporaneously herewith.

[3] Meet and confer telephone conferences were attended by David Raphael, Robin van der Meulen, Deborah Elman and Brian Brooks on behalf of Plaintiffs and Albert Manwaring on behalf of Alembic.

During the meet and confer process, Alembic asserted that the subpoenaed entity, Alembic Pharmaceuticals, Inc., was merely a U.S. sales and marketing subsidiary of Alembic India and that Alembic India had exclusive custody and control of all generic Exforge-related ANDA files, patent-related information, manufacturing and launch planning information, and documents forecasting/projecting of the impact of generic entry. Alembic stood on this objection and refused to produce ANDA files, Paragraph IV notice letters, and documents sufficient to show Alembic's manufacturing capabilities, forecasts/projections of the impact of generic entry, and launch planning/build-up. In addition, citing confidentiality concerns, Alembic has refused to produce its generic Exforge sales data with customer identifying information.[4]

On May 31, 2019, in an effort to reach agreement with Alembic and minimize any burden to complying with the subpoena, Plaintiffs requested that Alembic produce the ANDA for its generic version of Exforge, including all regulatory correspondence with FDA relating to that ANDA; any Paragraph IV correspondences between Alembic and Novartis, and Alembic's generic Exforge U.S. sales data, including customer identifying information. In addition, Plaintiffs proposed that counsel for Alembic inquire with both the Alembic parent company in India and the U.S. subsidiary and produce documents sufficient to show, for the time period from Alembic's ANDA filing through launch in November 2015: (1) generic Exforge launch planning/timing and execution including, but not limited to, process validation records, manufacturing of launch quantity buildup (scale-up), availability of active pharmaceutical ingredients ("API") and other excipients, equipment availability and readiness, batch sizes and manufacturing rates; (2) projections/forecasts regarding Alembic's generic Exforge launch date,

[4] Alembic stated that it would only be willing to produce sales data by class of customer (i.e., wholesaler or retailer) but, as explained below, data in this form is not sufficient.

the number of generic Exforge competitors, generic Exforge dollar and unit sales, generic Exforge substitution/penetration rate, and generic Exforge pricing; (3) the absence of logistical impediments (i.e., manufacturing capacity, access to materials, etc.) to an earlier launch; and (4) Alembic's willingness to launch earlier than November 2015.[5] Plaintiffs indicated that they would reserve the right to engage Alembic in further discussion if the "sufficient to show" production in these four categories was in some way not sufficient.

Counsel for Alembic did not respond to Plaintiffs' May 31st offer by the requested June 14, 2019 response date and still has not responded to that offer as of the date of this filing. In addition, counsel for Alembic has not responded to Plaintiffs' July 16, 2019 email correspondence indicating that Plaintiffs viewed Alembic's failure to respond as an indication that the meet and confer process was over and that Plaintiffs would be filing a Motion to Compel.[6]

III. LEGAL STANDARD

Rule 26(b)(1) provides that discovery encompasses that which "is relevant to any party's claim or defense and proportional to the needs of the case," and "need not be admissible in evidence to be discoverable." Fed. R. Civ. P. 26(b)(1). Relevancy is broadly construed for discovery purposes and is not limited to the precise issues set out in the pleadings or the merits of the case. *See Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340, 351 (1978) ("The key phrase in this definition—'relevant to the subject matter involved in the pending action'—has been construed broadly to encompass any matter that bears on, or that reasonably could lead to other matters that could bear on, any issue that is or may be in the case."). "Information is relevant if:

[5] *See* Exhibit 5, May 31, 2019 letter from Plaintiffs' counsel D. Raphael to Alembic's counsel A. Manwaring.

[6] *See* Exhibit 3, July 16, 2019 email from Plaintiffs' counsel D. Raphael to Alembic's counsel A. Manwaring.

(a) it has any tendency to make a fact more or less probable than it would be without the evidence; and (b) the fact is of consequence in determining the action." *N. Shore-Long Island Jewish Health Sys., Inc. v. MultiPlan, Inc.*, 325 F.R.D. 36, 47 (E.D.N.Y. 2018). "Once relevance has been shown, it is up to the responding party to justify curtailing discovery." *Fireman's Fund Ins. Co. v. Great Am. Ins. Co. of New York*, 284 F.R.D. 132, 135 (S.D.N.Y. 2012).

Motions to compel and motions to quash a subpoena are both "entrusted to the sound discretion of the district court." *In re Fitch, Inc.*, 330 F.3d 104, 108 (2d Cir. 2003) (citing *United States v. Sanders*, 211 F.3d 711, 720 (2d Cir. 2000)); *accord In re World Trade Ctr. Disaster Site Litig.*, No. 05-cv-9141, 2009 WL 4722250, at *2 (S.D.N.Y. Dec. 9, 2009) (Hellerstein, J.) (citing *In re Fitch*, 330 F.3d at 108). "Whether a subpoena imposes … an 'undue burden' depends upon 'such factors as relevance, the need of the party for the documents, the breadth of the document request, the time period covered by it, the particularity with which the documents are described and the burden imposed.'" *Concord Boat Corp. v. Brunswick Corp.*, 169 F.R.D. 44, 48-49 (S.D.N.Y. 1996) (quoting *U.S. v. IBM Corp.*, 83 F.R.D. 97, 104 (S.D.N.Y. 1979)); *see also In re Biovail Corp. Sec. Litig.*, 247 F.R.D. 72, 74 (S.D.N.Y. 2007) ("where, as here, [information] is sought from third parties, the Court must weigh the probative value of the information against the burden of production on said non-parties.").

IV. ARGUMENT

Alembic has yet to produce a single document in response to Plaintiffs' subpoena, which was served over eight months ago. The scope of the subpoena has been substantially narrowed through the now-stalled meet and confer process and the requested documents are relevant to Plaintiffs' claims in this action. These documents are not obtainable from the Defendants and should not be burdensome to produce. Plaintiffs' motion to compel should be granted.

A. Alembic's Generic Exforge Sales Data Is Relevant, Not Obtainable from Defendants, and Not Burdensome to Produce

Alembic's sales data is relevant and it is not burdensome to produce. Thus, the Court should promptly compel Alembic to produce the requested data through 2017.[7]

Request 7 of the subpoena seeks Alembic's generic Exforge transaction-level sales data, including data showing returns, chargebacks, rebates, and other price adjustments—basically data from which the Plaintiffs can calculate the net amount of generic Exforge purchased from Alembic and the net amount paid for this generic Exforge. This information is relevant to Plaintiffs' allegation that Novartis's and Par's anticompetitive conduct harmed Plaintiffs by causing them to pay higher prices than they otherwise would have. Plaintiffs must demonstrate antitrust impact (injury, in the form of higher prices, caused by the anticompetitive conduct) and class-wide damages (the difference between the brand and generic prices actually paid by Plaintiffs and the classes and the prices that would have been paid if generic Exforge had been available earlier). To calculate the net prices purchasers paid for generic Exforge, Plaintiffs need the prices purchasers from Alembic (and other generic Exforge sellers) paid. Alembic's sales data supplies inputs used to determine the amount of generic Exforge purchased, and the net prices actually paid for the generic. Plaintiffs and their experts will use these inputs to model the quantities that Plaintiffs would have purchased, and the (lower) prices Plaintiffs would have paid for brand and generic Exforge absent the anticompetitive conduct. Damages are the difference between what the Plaintiffs actually spent (the volumes purchased multiplied by the net prices paid) and what they would have spent absent the anticompetitive conduct (the modeled figures). *See, e.g.*, *In re Wellbutrin XL Antitrust Litig.*, No. 08-2431 (MAM), 2011 WL 3563385, at *14-

[7] Note that the Court recently granted Plaintiffs' motion to compel Defendants to produce branded and generic sales data through the end of 2017. *See* Order on Discovery, June 18, 2019, Dkt. No. 167.

15 (E.D. Pa. Aug. 11, 2011) (discussing "before and after" methodology, which "produces an aggregate damages estimate that is based on deriving a benchmark for generic prices in the 'but for world' based on the actual experience for branded and generic prices after entry"); *Meijer, Inc. v. Warner Chilcott Holdings Co. III*, 246 F.R.D. 293, 311-12 (D.D.C. 2007) (noting actual generic prices are used for damages calculation in delayed generic entry antitrust cases).

The transactional sales data sought by Request 7 of the subpoena is routinely requested and produced by non-parties—in this case and others—under similar circumstances, usually voluntarily but by court order if needed. *See, e.g., Direct Purchaser Class v. Apotex Corp.*, No. 16-62492-mc (WJZ), 2017 WL 4230124, at *2-5 (S.D. Fla. May 15, 2017) (enforcing non-party subpoena in antitrust case involving delayed generic entry that sought "sales data for generic Celebrex and/or authorized generic Celebrex in electronic format, at the transaction level" because such data would allow plaintiffs' economic experts to determine price for generic Celebrex absent defendant's anticompetitive conduct); *In re Namenda Direct Purchaser Antitrust Litig.*, 15-civ-7488 (CM) (JCF), 2017 WL 4700367, at *2-3 (S.D.N.Y. Oct. 19, 2017) ("*Namenda II*") (ordering non-party generic to produce transactional sales data in an antitrust case because monthly sales summaries were inadequate and stating that "[t]here is little question that the transactional sales information sought by plaintiffs is relevant"). Antitrust cases require substantial data analysis. *See Mitsubishi Motors Corp. v. Soler Chrysler-Plymouth, Inc.*, 473 U.S. 614, 632 (1985) ("antitrust issues, prone to complication, require sophisticated legal and economic analysis"). Accordingly, "the production of voluminous transactional data . . . in an antitrust case is routine and happens in every case." F. Matthew Ralph & Caroline B. Sweeney, *E-Discovery and Antitrust Litigation*, 26 ANTITRUST 58, 61 (2011) (quotation and citation omitted); *see also, e.g., Valley Drug Co. v. Geneva Pharm., Inc.*, 350 F.3d 1181, 1192 (11th Cir.

2003) (district court erred by prohibiting certain data discovery).

Alembic has objected to producing the requested data on confidentiality grounds but, as Plaintiffs explained to Alembic,[8] any such confidentiality concerns are adequately addressed by the Stipulated Protective Order in this case (ECF No. 95, which was attached to the subpoena to Alembic), which allows Alembic to designate its data production as "Confidential" or "Highly Confidential" as appropriate pursuant to the Stipulated Protective Order, in order to ensure and protect the confidentiality of Alembic's confidential information. Courts have ordered production of this same transaction-level sales data (with customer names) over similar confidentiality objections in other cases. *See Apotex Corp.*, 2017 WL 4230124, at *5 (compelling production of third party's sales data and finding that the "Protective Order will provide sufficient protection of Respondent Apotex Corp.'s sales data"). *See also In re K-Dur Antitrust Litig.*, No. 03-21589-civ (UUB) (STB), 2003 WL 27375780, at *2 (S.D. Fla. Aug. 21, 2003) (third party's confidentiality concern "is addressed by the implementation of an appropriate confidentiality order, which is already in place in this case, and to which Andrx has voiced no objection."); *Truswal Sys. Corp. v. Hydro-Air Eng'g, Inc.*, 813 F.2d 1207, 1211 (Fed. Cir. 1987) ("The normal and expected reluctance of business firms to disclose sales information, however, is in itself an insufficient basis on which to deny discovery of that information under appropriate protection from divulgement to competitors.").

To the extent that Alembic asserts relevancy objections to its customer name information, the customer name information is relevant and necessary to identify the volume of Alembic's generic sales made to members of the Direct Purchaser Class (as opposed to non-class members)

[8] *See* Exhibit 4, February 22, 2019 letter from Plaintiffs' counsel D. Raphael to Alembic's counsel A. Manwaring, at 3; *see also* Exhibit 5, May 31, 2019 letter from Plaintiffs' counsel D. Raphael to Alembic's counsel A. Manwaring, at 2-3.

and the prices that members of the Direct Purchaser Class actually paid, which is relevant to Plaintiffs' damages calculations, as well as to the allocation of damages following judgment. Alembic's proposal to produce sales data by class of customer (i.e., wholesaler or retailer) is thus insufficient because such data would not allow Plaintiffs to identify purchases by Class members.

Alembic has articulated no burden to producing the requested data (including the requested customer names), nor is there any. Alembic's data can be readily accessed through a direct pull from Alembic's central servers. *See Namenda II*, 2017 WL 4700367, at *3 (granting motion to compel production of non-party generic manufacturer's sales data over manufacturer's "unpersuasive" burden argument); *Kleen Prods. LLC v. Packaging Corp. of Am.*, No. 10-c-5711 (HDL), 2013 WL 120240, at *9 (N.D. Ill. Jan. 9, 2013) (granting plaintiffs' motion to compel the production of pre- and post- class period documents and transactional data in light of the "expansive view of discovery in antitrust cases" and "defendants' lack of demonstration of burden").

Indeed, the Court previously granted a motion to compel similar sales data, ordering the Defendants, Novartis and Par, to produce brand and generic Exforge sales data through 2017. *See* Dkt. No. 167.

B. Alembic's Generic Exforge Regulatory Files Are Relevant, Not Obtainable from Defendants, and Not Burdensome to Produce

Alembic should also be compelled to promptly produce its generic Exforge ANDA file—including all ANDA filings and related correspondence, internally and with the FDA, as sought in Request 3—because these documents are relevant and not burdensome to produce.

Alembic's ANDA file for generic Exforge is relevant to Plaintiffs' allegation that absent Novartis's and Par's anticompetitive conduct, Alembic would have launched its generic version

of Exforge sooner, resulting in purchasers paying lower prices earlier than they actually did. Indeed, Alembic's ANDA file contains critical information regarding any regulatory issues Alembic experienced in seeking FDA approval of its generic Exforge ANDA and the steps and time Alembic took to resolve those issues. Alembic's internal communications regarding the status and priority assigned to prosecuting its ANDA are relevant to understanding the efforts and amount of time Alembic expended to resolve regulatory issues involving its ANDA as well as the motives and incentives affecting Alembic, and the extent to which the challenged settlement agreement between Novartis and Par affected those motives and incentives. Such information is also relevant to establishing the date on which Alembic would have launched generic Exforge absent the challenged conduct. Alembic's ANDA file also contains information necessary to support any non-infringement position it offered in its Paragraph IV correspondences (*see* Section E, below). Alembic's ANDA file is thus relevant to Plaintiffs' calculation of damages.

Plaintiffs and Defendants do not possess Alembic's ANDA file, so these relevant documents must be obtained from Alembic. And, once again, Alembic has not articulated any burden associated with production of these documents, nor can it, given that Alembic is required by regulations to store its ANDA files in a single, easy to access location such that it can be available for verification "at all reasonable times." 21 U.S.C. § 355(k)(2).

Alembic claims that the ANDA documents and other requested documents are in the custody and control of its parent company in India, but as Plaintiffs explained to Alembic, mere possession by a foreign parent is not dispositive,[9] *see, e.g.*, *Cooper Indus., Inc. v. British Aerospace, Inc.*, 102 F.R.D. 918, 920 (S.D.N.Y. 1984) ("the fact that the documents are situated

[9] *See* Exhibit 4, February 22, 2019 letter from Plaintiffs' counsel D. Raphael to Alembic's counsel A. Manwaring, at 3.

in a foreign country does not bar their recovery"), and courts have ordered the production of documents held by a foreign parent. *See Ferber v. Sharp Elecs. Corp.*, No. 84-civ-3105 (RO) (MHD), 1984 WL 912479, at *1-3 (S.D.N.Y. Nov. 28, 1984) (ordering production from domestic subsidiary of documents in possession of Japanese parent.). Where a subsidiary has the practical ability to obtain documents from its parent corporation, the documents are within its control. *See In re Namenda Direct Purchaser Antitrust Litig.*, No. 15-civ-7488 (CM) (JCF), 2017 WL 3822883, at *7 (S.D.N.Y. Aug. 30, 2017) ("*Namenda III*") (where the U.S. subsidiary must contact its corporate parent in India to identify which department and custodians are likely to have responsive information documents and then arrange a search, the argument "does not seem to be that [the corporate parent in India]'s documents are not within [the U.S. subsidiary]'s control, but rather that providing them will involve some burden."); *Ferber*, 1984 WL 912479, at *2 (motion to compel granted where "the subsidiary and parent have worked sufficiently closely in the particular field of endeavor that is subject of the lawsuit to suggest that the subsidiary could be deemed to have constructive control of the information sought – that is, the ready ability to obtain it – even if not actual possession.").

Here, Alembic counsel's offers during meet and confers to obtain and produce certain documents that it stated were in the possession of the corporate parent in India[10] confirms that

Alembic can access and produce these documents.

With respect to ANDA files in particular, the FDA's contact with Alembic India's U.S. subsidiary is the equivalent of contact with the foreign parent as a matter of law. *See* 21 C.F.R. 207.69(b)(4). Therefore, although the files are not required to be physically present in the U.S.,

[10] *See* Exhibit 3, January 16, 2019 email from Alembic's counsel A. Manwaring to Plaintiffs' counsel B. Brooks and others; *see also* Exhibit 3, March 14, 2019 email from Alembic's counsel A. Manwaring to Plaintiffs' counsel D. Raphael and others.

the U.S. subsidiary (Alembic, the subpoenaed party here) must be able to expeditiously access and produce them. Given the applicable laws and regulations, there should be little, if any, burden associated producing these regulatory files in this litigation.

C. Alembic's Manufacturing and Launch Documents Are Relevant, Not Obtainable from Defendants, and Not Burdensome to Produce.

Evidence that, absent Defendants' conduct, Alembic would have been ready, willing, and able to market generic Exforge earlier than November 2015, when Alembic's ANDA product actually launched after Par's 180-day exclusivity ended, is relevant to Plaintiffs' proof of causation and damages. Courts have recognized in similar delayed-generic-entry pharmaceutical antitrust cases that evidence of when and whether other generic manufacturers would have been ready, willing, and able to market the generic products earlier was relevant to issues of, without limitation, causation and damages. *Supra at 2, citing Namenda I*, 331 F. Supp. 3d at 169-72; *Neurontin*, 2013 WL 4042460, at *9-10. *See also Namenda III*, 2017 WL 3822883, at *5 (documents sought are "integral to a meaningful understanding of the company's efforts to launch the product").

Because Plaintiffs allege that later-filing generics, such as Alembic, would have been ready, willing, and able to launch earlier absent the Novartis-Par agreement, Alembic's documents are relevant to show whether it had the capability, equipment, manpower, facilities, ingredients, packaging, planning, regulatory approval (or ability to obtain such approval), and other capabilities necessary to effectuate an earlier launch. Moreover, Plaintiffs cannot obtain this information about Alembic from any entity other than Alembic.

Request Nos. 4 and 5 are narrowly tailored to cover Alembic's readiness, ability, and/or willingness to launch its generic Exforge product earlier, or the timing of when Alembic would have launched generic Exforge absent Defendants' allegedly unlawful conduct. Further, in an

effort to mitigate any burden on Alembic, including any burden that might be associated with making reasonable inquiries with Alembic's parent company in India, Plaintiffs have agreed to narrow Requests 4 and 5 and accept documents sufficient to show, for the time period from Alembic's ANDA filing through launch in November 2015: (1) generic Exforge launch planning/timing and execution including, but not limited to, process validation records, manufacturing of launch quantity buildup (scale-up), availability of API and other excipients, equipment availability and readiness, batch sizes and manufacturing rates; (2) the absence of logistical impediments (i.e., manufacturing capacity, access to materials, etc.) to an earlier launch; and (3) Alembic's willingness to launch earlier than November 2015.[11] Plaintiffs would reserve the right to engage Alembic in further discussions if issues arise as to the sufficiency of this "sufficient to show" production.

Other than generally raising issues regarding the custody and control of documents that Alembic claims are in the possession of its parent company in India (which, as discussed above, is not dispositive on the issue of whether production is required), Alembic has not made any effort to demonstrate that the production of this information would be unduly burdensome, as it is required to do. *See Namenda III*, 2017 WL 3822883, at *6 (rejecting a third party subpoena target's unsubstantiated burden claim as "anemic"). The Court must weigh the burden to the subpoenaed party against the value of the information to the serving party. This analysis depends upon factors such as relevance, the need of the party for the documents, the breadth of the document request, the time period covered by it, the particularity with which the documents are described and the burden imposed. *See AmTrust N. Am., Inc. v. Preferred Contrs. Ins. Co. Risk Retention Grp., LLC*, No. 16-mc-0340 (CM), 2016 WL 6208288, at *4 (S.D.N.Y. Oct. 18, 2016)

[11] *See* Exhibit 5, May 31, 2019 letter from Plaintiffs' counsel D. Raphael to Alembic's counsel A. Manwaring, at 1.

(rejecting burden claim). Here, Alembic has not substantiated its objections by "detailing the volume of documents at issue or the number of personnel hours that would be necessary to produce the [requested] documents," *Namenda III*, 2017 WL 3822883, at *6, so there is no basis upon which the Court could conclude that compliance with Plaintiffs' narrowed requests regarding manufacturing and launch documents would be unduly burdensome to Alembic.

D. Alembic's Forecasting and Projection Documents Are Relevant, Not Obtainable from Defendants, and Not Burdensome to Produce

Alembic should also be compelled to promptly produce its generic Exforge forecasting and projection documents, as requested by Requests 2, 4, 12, and 13, because these documents are relevant and not burdensome to produce.

Alembic's forecasts and launch plans for its generic version of Exforge and related documents are relevant to Plaintiffs' claims, as they reflect a knowledgeable market participant's contemporaneous expectations of the timing and impact of generic entry on (a) brand and generic market share, and (b) market prices. In addition, Alembic's pre-settlement forecasts and launch plans are probative of when Alembic believed generic competition would have begun absent the challenged delay in generic competition, and what the effect of that earlier competition would have been on brand and generic Exforge units and prices. Plaintiffs' experts are permitted to and often do use the forecasts of knowledgeable market participants like Alembic to determine what the price of a generic drug would have been as a function of the number of generic firms expected to enter the market, and what generic market share would have been based on the timing of forecasted generic entry. *See, e.g.*, *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, No. 14-md-02503 (DJC), 2017 WL 4621777, at *7-9 (D. Mass. Oct. 16, 2017) (certifying a class of direct purchasers where the plaintiffs' expert (a) relied on nonparty and party generic company forecasts as common evidence of classwide impact, and (b) used these

generic company forecasts to calculate what the generic market share would have been, and damages); *In re Lidoderm Antitrust Litig.*, No. 14-md-02521 (WHO), 2017 WL 679367, at *9-10 (N.D. Cal. Feb. 21, 2017) (certifying the direct purchaser class in a similar case challenging a "no-authorized generic" promise where the plaintiffs' expert relied on generic company forecasts as one form of evidence of classwide impact); *Wellbutrin XL*, 2011 WL 3563385, at *12 (class certification granted where plaintiffs' evidence of classwide injury included nonparty generic company forecasts); *In re Neurontin Antitrust Litig.*, Nos. 02-1830 (FSH), 02-2731 (FSH), 2011 WL 286118, at *7-8 (D.N.J. Jan. 25, 2011) (same); *Teva Pharms. USA, Inc. v. Abbott Labs.*, 252 F.R.D. 213, 229 (D. Del. 2008) (same). Manufacturers' sales forecasts (like those requested from Alembic) also typically reflect the expectation that all generic sales would be taken from the corresponding brand (here, branded Exforge), not from other, non-bioequivalent products, which is probative of the composition of the relevant antitrust market.

Plaintiffs have offered to narrow the forecasting requests to documents sufficient to show, for the time period from Alembic's ANDA filing through launch in November 2015, projections and forecasts regarding Alembic's generic Exforge launch date, number of generic Exforge competitors, generic Exforge dollar and unit sales, generic Exforge substitution/penetration rate, and generic Exforge pricing, yet Alembic has failed to produce any of the requested documents.

Defendants do not possess Alembic's forecasts or launch plans so these relevant documents must be obtained from Alembic. And again, other than the general objection that documents are in the possession of Alembic's parent company in India, Alembic has not articulated any burden objection, nor can it. *See Namenda III*, 2017 WL 3822883, at *6 (rejecting a third party subpoena target's unsubstantiated burden claim as "anemic"); *AmTrust N.*

Am., Inc. v. Preferred Contrs. Ins. Co. Risk Retention Grp., LLC, No. 16-mc-0340 (CM), 2016 WL 6208288, at *4 (S.D.N.Y. Oct. 18, 2016) (rejecting burden claim), *citing Copantitla v. Fiskardo Estiatorio, Inc.*, No. 09 CIV. 1608, 2010 WL 1327921, at *10, *32 (S.D.N.Y. Apr. 5, 2010). Alembic has not substantiated its objections by "detailing the volume of documents at issue or the number of personnel hours that would be necessary to produce the [requested] documents." *Namenda III*, 2017 WL 3822883, at *6. Alembic should thus be compelled to produce these documents because their relevance far outweighs any burden to Alembic.

E. Alembic's Paragraph IV Correspondences are Relevant and Not Burdensome to Produce

Finally, Alembic should be compelled to promptly produce any Paragraph IV Certification notice letters sought by Request 1 because these documents are relevant and not burdensome to produce.

Alembic's Paragraph IV notices are relevant because they alert Novartis of the bases for Alembic's claim that its proposed generic product did not infringe the patents listed in the Orange Book as covering Exforge and/or that those patents were invalid or unenforceable. Novartis's views of its chances of success in the patent litigation, informed in part by the generic ANDA filers' Paragraph IV notification letters, will be used by Plaintiffs' patent experts as well as their causation experts to determine feasible dates of market entry for generic Exforge absent the unlawful agreement between Par and Novartis.

This request seeks production of what is likely a single document located in a known location in the files of Alembic and/or its corporate parent. Here again, Alembic has not substantiated its objections by "detailing the volume of documents at issue or the number of personnel hours that would be necessary to produce the [requested] documents." *Namenda III*,

2017 WL 4700367, at *6. Alembic has should thus be compelled to produce the relevant, responsive documents.

V. CONCLUSION

The documents sought by Plaintiffs' subpoena are relevant, appropriately limited in scope, and not unduly burdensome for Alembic to collect and produce. Indeed, Alembic has not articulated any burden to production. For the foregoing reasons, Plaintiffs respectfully request that this Court grant Plaintiffs' Motion to Compel and order Alembic to promptly produce the following categories of documents: (a) Alembic's generic Exforge sales data; (b) relevant documents from Alembic's Abbreviated New Drug Application ("ANDA") file for its generic Exforge product; (c) Alembic's documents relating to manufacturing capabilities, launch planning, and launch decision making; (d) Alembic's projections and other forecasting documents regarding the potential market entry of generic versions of Exforge; and (e) Alembic's Paragraph IV notice to Novartis challenging Novartis's patent(s) related to Exforge. These documents and data are responsive to Plaintiffs' subpoena Request Nos. 1, 3 and 7, and Nos. 2, 4, 5, 12, and 13 as narrowed in Plaintiffs' May 31, 2019 letter to Alembic (Ex. 5).

Dated: August 1, 2019

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on August 1, 2019, I, Dan Litvin, served the above Memorandum of Law via ECF on all counsel of record and via Federal Express on third party Alembic Pharmaceuticals, Inc.

Dated: August 1, 2019

Respectfully Submitted,

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